REMARKS

Support for the amendment of claims **2** and **5** may be found in page 16, lines 20-21 and page 17, lines 4-5, and pages 13-14. Support for the amendment of claims **14, 17, 20, 23, 26, 29, 32, 35, 86** and **89** may be found in pages 13-4, 16 lines 20-21. Accordingly, no new matter has therefore been introduced.

In the 06/13/2005 Office Action, the Examiner has rejected claims **2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87** and **89-90**. After entry of the instant amendment, claims **2, 5, 14, 17, 20, 23, 26, 29, 32, 35, 86** and **89** remain pending in the application. Reconsideration and allowance of all pending claims **2, 5, 14, 17, 20, 23, 26, 29, 32, 35, 86** and **89** is respectfully requested.

35 U.S.C. §112

Claims **2-3, 5-6, 8-9, 11-12, 14-15, 17-28, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87** and **89-90** stand rejected under 35 U.S.C. §112 as purportedly comprising new subject matter. The Examiner proposes that "the two limitations 'the composition further comprising one or more of the salts of fatty acids according to the formula R^1-COO^-M^+ wherein R1 comprises CH3-(CH2)7-CH=CH-CH2-(CH20x-, and x is 6, 8, 10 and12 and M+ is a monovalent alkali metal ion' and 'wherein the composition further comprises one or more mixed esters according to the formula R1-COO-R2 wherein R1 comprises CH2-(CH2)7-CH=CH-CH2-(CH2)x-, and x is 6, 8, 10 and 12, and R2 is an alkyl group or other aliphatic group, preferably of 1 to 12 carbon atoms' are essential and critical elements of the claimed invention".

In view of Applicant's instant amendment, the Examiner's objections with respect to 35 U.S.C. §112 have been obviated. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112 be withdrawn.

35 USC § 103(a)

Claims **2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87**, and **89-90** stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Katz *et al.* (US 5,952,392) in view of Arquette *et al.* (WO 9920224), Katz (US 4,874,794) and Katz (US 5,070,107). Applicants respectfully

traverse this rejection. Furthermore, Applicants respectfully request clarification as to several propositions presented by the Examiner in the 06/13/2005 Office Action.

On page 6 lines 12-13 of the Office Action, the Examiner cites "col. line 5-8" in Katz *et al.* (US 5,952,392). Applicants are affirmatively unaware as to which column the Examiner intends to reference, and therefore request clarification so that the record of prosecution may be rendered clear. The Examiner also states on page 6 lines 21-24 of the pending Office Action, "Katz *et al.* also discloses that the effective amount of docosenol in the pharmaceutical composition is about 10% to 12% w/w (by weight, within the instant claim, see col.6 line 64, col.16 lines 59-60 and claims 10-11)." The Applicant is affirmatively unaware as to which Katz reference the Examiner intends to reference, inasmuch as three different Katz patents (US 5,952,392, US 4,874,794 and US 5,070,107) were presented by the Examiner as purportedly constituting prior art.

On page 8 lines 7-16 of the Office Action, the Examiner states "[O]ne having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant monounsaturated long chain alcohols in combination with the instant fatty acids salts herein a pharmaceutical composition,...for methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity based on Katz *et al.*". Applicants are affirmatively unaware as to which Katz reference the Examiner intends to refer to, inasmuch as three different Katz patents were presented by the Examiner as purportedly constituting prior art. Clarification on this point is respectfully requested so that the record of prosecution may be rendered clear.

On page 8 lines 17-18 of the Office Action, the Examiner proposes that "the instant fatty alcohols at least 10% by weight, or about 10% to 12% w/w by weight of docosenol in the pharmaceutical composition disclosed by Katz *et al.* (5,952,392)". The Applicant is affirmatively unaware as to where in Katz *et al.* (5,952,392) **docosenol** is mentioned (*emphasis added*). Applicants respectfully submit that one with ordinary skill in the art would appreciate that **docosanol**, as disclosed in Katz *et al.* (5,952,392), is distinct from **docosenol**, as disclosed in the present invention (*emphasis added*).

On page 9 lines 21-22 of the pending Office Action, the Examiner refers to "optimization of known effective amounts of known active agents to be administered according to disclosure of Katz et al. and Arquette et al.". Applicants are affirmatively unaware as to which Katz reference the Examiner intends to reference, inasmuch as three different Katz patents were presented by the Examiner as purportedly constituting prior art.

Applicants respectfully request clarification on these points, so that the record of prosecution may be rendered clear on potential Appeal. Furthermore, Applicants respectfully requests that the next Office Action be reset to a non-final status in order to provide Applicants with full and fair opportunity to respond to all of the Examiner's rejections on the merits.

That notwithstanding, the Examiner proposes that Katz *et al.* (US 5,952,392) discloses long chain fatty acids, or monounsaturated long chain alcohols with physiologically compatible carriers, as useful in a pharmaceutical compositions because of their antiviral activity. However, nowhere does Katz *et al.* (US 5,952,392) disclose, teach or otherwise describe salts of fatty acids in combination with monounsaturated alcohols (much less, in combination with mixed esters) as recited in claims **2, 14, 20, 26, 32,** and **86** as amended.

The Examiner then goes on to propose that Arquette *et al.* (WO 9920224) discloses "pharmaceutical compositions comprising the instant fatty alcohols at least 10% by weight ... jojoba oil (known to contain instant fatty acids, see page 4 entirely), and the instant fatty acid esters in their various percentages (see page 4-8) with a physiologically compatible carrier for topical applications". Applicants respectfully submit that jojoba oil contains esters of fatty acids but **no fatty acids** as the Examiner contends (emphasis added). Moreover, skilled artisans appreciate that jojoba does not contain fatty acids, but rather esters of fatty acids. Thus, Arquette *et al.* (WO 9920224) does not disclose, teach or otherwise suggest long chain fatty acids in combination with long chain alcohols as recited in claims **2, 14, 20, 26, 32,** and **86** as amended.

The Examiner then proposes that Katz *et al.* (US 4,874,794) discloses that "the effective amounts of long chain fatty alcohols broadly (*e.g.*, C20-C26) with a physiologically compatible carrier in a pharmaceutical composition... are 01. to 25 percent by weight". Applicants respectfully submitted that the Katz *et al.* reference (US 4,874,794) does not disclose use of **mono-unsaturated** alcohols in combination with salts of fatty acids as recited in Applicants' claims **2, 14, 20, 26, 32,** and **86** as amended.

The Examiner suggests that Katz *et al.* (US 5,070,107) discloses "effective amounts of long chain fatty alcohols broadly (*e.g.* C27-C32) with a physiologically compatible carrier in a pharmaceutical composition for topical application and intramuscular and intravenous injections for methods of treating viral infections and skin inflammations are 01. mg to 2g/per 50kg of body weight"; however, this is not the case. Nowhere in Katz *et al.* (US 5,070,107) is the composition of salts of long chain fatty acids in combination with monounsaturated alcohols (much less, in combination with mixed esters) disclosed, taught or otherwise suggested as recited in Applicants' claims **2, 14, 20, 26, 32,** and **86** as amended.

Applicant respectfully disagrees with the Examiner concerning the proposed combination of Katz *et al.* (US 5,952,392), Arquette *et al.* (WO 9920224), Katz (US 4,874,794) and Katz (US 5,070,107).

Applicants respectfully submit that a *prima facie* case of obviousness has not been established. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP, 2143). Additionally, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not in Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Examiner suggests "one having ordinary skill in the art at the invention was made would have been motivated to combine monounsaturated long chain alcohols and fatty acids" because each are purportedly known to have anti-viral activity. Notwithstanding Applicant's arguments presented *vide supra*, the Examiner's rejection in the instant case fails to provide motivation to combine the cited references – and even if the references were to be combined, they would not teach or suggest the combination of monounsaturated long chain alcohols **and** fatty acid **salts** and **mixed esters** in a physiologically active pharmaceutical composition, as recited in all of Applicants' pending claims as amended. Accordingly, Applicants' instant amendments have rendered the Examiner's rejections in this regard moot.

The Examiner goes on to suggest that "the instant fatty alcohols at least 10% by weight, or about 10% to 12% w/w by weight of docosenol in the pharmaceutical composition disclosed by Katz *et al.* (5,952,392), or 0.1 mg to 2 g/per 50kg of body weight also disclosed by Katz *et al.* (5,070,107) and (4,874,794), the instant fatty acids, and the instant fatty acid esters in various percentages with a physiologically compatible carrier are known to be useful in a pharmaceutical composition for topical applications according to Arquette *et al.*". Notwithstanding Applicants'arguments *vide supra* that **docosanol**, as disclosed in Katz *et al.* (5,952,392), is distinct from **docosenol**, as disclosed in Applicants' invention, skilled artisans would not have been motivated to combine **salts** of fatty acids with the monounsaturated long chain alcohols disclosed and claimed in Applicant's invention to achieve a substantially similar result. The combination of the claimed salts of fatty acids with monounsaturated long chain alcohols produces an unexpected synergistic effect, which exceeds the discrete additive combination of the individual components.

To rebut this, the Examiner claims "[I]t has been well settled that pharmaceutically acceptable salts of the pharmaceutical compound are obvious over the pharmaceutical compound." Later, the Examiner cites MPEP §2143.02 for the same proposition. To the extent that MPEP §2143.02 relies on *In re Merck & Co.*, 800 F.2d 1091 (Fed. Cir. 1986) for this proposition, the Applicant respectfully traverses. In *In re Merck*, the method of treating depression with amitriptyline (or the non-toxic salts thereof) was found obvious in light of prior art, comparing the claimed compound to a structurally similar psychotropic compound known to possess antidepressive properties, suggested by clinical testing of amitriptyline as an antidepressant. *See* MPEP §2143.02 (discussing *In re Merck & Co.*). In the case of Applicants' invention, there is no prior art which has suggested that long chain monounsaturated alcohols in combination with salts of fatty acids according to the present invention would possess antiviral effects. Therefore, the precedent of *In re Merck & Co.*, as indirectly cited by the Examiner, is not applicable.

Further, the Examiner states "the same fatty acid salts are deemed obvious over the same fatty acids taught by the cited prior art, having the same therapeutic effects and usefulness in treating virus-induced and inflammatory diseases of skin and membranes". The Examiner also cites *In re Kerkoven*, 205 USPQ 1069 (CCPA 1980) for the proposition that "at least additive therapeutic effects would have been reasonably expected". However, the Applicant is affirmatively unable to determine where in *In re Kerkoven* such a proposition has been stated. Clarification on this point is respectfully requested, so that the record of prosecution may be rendered clear on potential Appeal.

That notwithstanding, Applicants' respectfully disagree with the Examiner's arguments. Specifically, Applicants remind the Examiner that it is the *combination* of long chain monounsaturated alcohols and fatty acid salts as claimed in the present invention that create an unexpected, synergistic effect that cannot be deduced from any of the prior art references, either taken alone or in combination. Additionally, all pending claims in the instant application have been amended to include the further limitation of inclusion of mixed esters

The Examiner has also cited *In re Boesh*, 617 F.2d 272 (C.C.P.A. 1980) for the proposition that "it is well within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect". However, Applicants' respectfully point out that *In re Boesh*, 617 F.2d 272, 276 (C.C.P.A. 1980) goes on to state "[...] where the results of optimizing a variable, which was known to be result effective, are unexpectedly good". In this instance, skilled artisans would not have been motivated to combine the salts of fatty acids with the long chain monounsaturated long chain alcohols disclosed and claimed in Applicant's invention to achieve a substantially similar result. The

combination of the claimed fatty acid salts with the disclosed monounsaturated long chain alcohols produces an unexpected synergistic effect which exceeds the discrete additive combination of the individual components.

Accordingly, Applicants' submit that there is no motivation or suggestion to be found in Katz *et al.* (US 5,952,392), Arquette *et al.* (WO 9920224), Katz (US 4,874,794) and/or Katz (US 5,070,107), nor in the knowledge generally available to one of ordinary skill in the art, to modify any of the cited references with any other reference of record to practice the invention of Applicants' claims as amended.

Because there is no motivation or suggestion to combine Katz *et al.* (US 5,952,392), Arquette *et al.* (WO 9920224), Katz (US 4,874,794) and/or Katz (US 5,070,107) with any other reference to practice Applicants' invention, there can be no reasonable expectation of success. Where no motivation to combine can be found, any expectation of success concerning the proposed combination could only be unreasonable at best. Accordingly, Applicants' pending claims may not properly be regarded as obvious under § 103(a). See, for example, *Akamai Technologies, Inc. v. Cable & Wireless Internet Services, Inc.*, 344 F.3d 1186 (Fed. Cir. 2003) (There must be some teaching, suggestion, or motivation to combine references.); *Teleflex, Inc. v. Ficosa North American Corp.*, 299 F.3d 1313 (Fed. Cir. 2002) (The showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence.) (citing *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999)); *Carella v. Starlight Archery*, 804 F.2d 135 (Fed. Cir. 1986) (Obviousness cannot be established by combining teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting a combination.); *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984) (The fact that the prior art could be modified so as to produce the claimed invention is not a basis for an obviousness rejection, unless the prior art suggested the desirability of the modification.); and *Ex parte Walker*, 135 USPQ 195 (POBA 1961) (A combination of teachings must be proposed and the art should contain some suggestion of the desirability of making the proposed combination.)

"With respect to core factual findings in a determination of patentability, [the Examiner] cannot simply reach conclusions based on [his/her] own understanding or experience – or on [his/her] assessment of what would be basic knowledge or common sense. Rather [the Examiner] must point to some concrete evidence in the record in support of these findings." *In Re Zurko*, 258 F.3d 1379 (2001).

Accordingly, claims **2**, **5**, **14**, **17**, **20**, **23**, **26**, **29**, **32**, **35**, **86**, and **89** may not properly be considered as obvious under § 103(a). Applicants therefore respectfully request that the Examiner withdraw the § 103(a) rejections of the same.

CONCLUSION

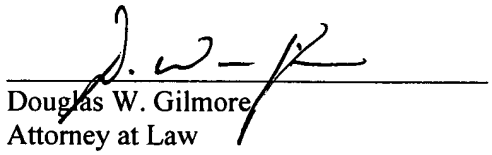
The remaining cited references have been reviewed and are not believed to affect the patentability of the claims as amended. Claims **2, 5, 14, 17, 20, 23, 26, 29, 32, 35, 86** and **89** are pending in the application. Reconsideration and allowance of all pending claims **2, 5, 14, 17, 20, 23, 26, 29, 32, 35, 86** and **89** is earnestly requested.

No amendment made herein was related to the statutory requirements of patentability unless expressly stated; rather any amendment not so identified may be considered as directed *inter alia* to clarification of the structure and/or function of the invention and Applicants' best mode for practicing the same. Additionally, no amendment made herein was presented for the purpose of narrowing the scope of any claim, unless Applicant has argued that such amendment was made to distinguish over a particular reference or combination of references. Furthermore, no election to pursue a particular line of argument was made herein at the expense of precluding or otherwise impeding Applicants from raising alternative lines of argument later during prosecution. Applicants' failure to affirmatively assert specific arguments is not intended to be construed as an admission to any particular point raised by the Examiner.

Should the Examiner have any questions regarding this Response and Amendment, or feel that a telephone call to the undersigned would be helpful to advance prosecution of this matter, the Examiner is invited to call the undersigned at the number given below.

Respectfully submitted,
ATTORNEY FOR APPLICANT

Date: 12/13/2005



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